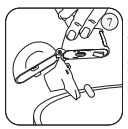


5. Breathe out completely.

Important: Please do not breathe into the mountpiece at any time.



6. Lift the inhaler to your mouth and close your lips tightly around the mountpiece. Hold your head upright and take a slow and deep breath. Adjust your breathing rate to hear or feel the capsule vibrating. Take breathe until your lung are full; hold your breath for a period that will not compel to you and remove the inhaler from your mouth. Now you can start breathing normally. Repeat steps 5 and 6 once more, this will ensure complete emptying of the capsule.



7. Open the mouthpiece again. Turn the device and discard the used capsule. Use a dry handkerchief or a soft brush to remove any remaining dust. Close the mouthpiece and dust cap and leave your device.

NOTE: **DO NOT USE WATER** to clean the inhaler. The capsules should not be exposed to extreme temperatures. AIREST inhaler capsules contains powder small amount, for this reason, capsules are partially filled.

#### Questions and answers about administration

1. How do I prevent the capsules from breaking into small particles? During the use of the device, the capsules may break and small particles may escape into your mouth or throat while breathing. You can avoid this the following by applying:

- Holding the capsules in their original packaging (blister packages) before use.
- Keeping the capsules at room temperature below 30°C.
- By protecting the capsules from moisture.

2. Are capsule particles harmful?

No. Capsule have been made from non-harmful gelatine. Gelatine particles going down your mouth or throat may be swallowed.

3. How can I take out the capsule stuck in the inhaler device?

Turn the device on, turn it upside down, and gently hit the base.

4. How can I sure if I actually took the truth dose?

- You will understand that the capsule vibrates when you breathe through the device.

- You will feel the 'sugar taste' from lactose in your mouth. You may feel powder in the back of your throat. This is normal.

5. How can I clean powder in device?

- Use a dry handkerchief or a soft brush to clean
- Do not forget that you do not need washing device.

#### Different age groups

**Use in children:** Children 4 to 12 years of age is using for inhalation powder of AIREST 50/100 micrograms capsule. There is no data available for children under 4 years of age.

#### Use in the elderly:

The dose adjustment is not necessary.

#### Special population:

**Renal/Hepatic impairment:** The dose adjustment is not necessary for patients with renal or hepatic impairment.

*If you have an impression that the efficacy of AIREST is too strong or weak, talk to your doctor or pharmacist.*

#### If you use more AIREST than you should:

*If you use more AIREST than you should, talk to your doctor or pharmacist.*

#### If you forget to use AIREST:

If you forget to use AIREST, you will take the next dose on time. *Do not take a double dose to make up for a forgotten dose.*

#### Effects that may occur when treatment of AIREST ends:

In patients with asthma, AIREST treatment should not be suddenly discontinued, and the dose of treatment should be progressively reduced under the supervision of a doctor. This can worsen your breathing problems and rarely cause serious side effects. These include that following:

- Stomach pain
- Tiredness and appetite lost
- Nausea and vomiting
- Weight loss
- Headaches and dizziness
- Decreased potassium levels in your blood
- Low blood pressure and seizures

In patients with COPD, discontinuation of treatment may lead to symptomatic decompensation (inability to operate the organ), and the treatment should be discontinued under the supervision of a doctor.

#### 4. Possible side effects

Like all medicines, AIREST may cause side effects, although not everybody gets them. To reduce the chance of side effects, your doctor will prescribe the lowest dose of AIREST to control your asthma

#### Very Common (affects more than 1 person in 10)

- Headache - this usually gets better as treatment continues.
- Increased number of colds have been reported in patients with COPD.

#### Common (affects less than 1 person in 10)

- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also sore tongue and hoarse voice and throat irritation. Rinsing your mouth out with water and spitting it out immediately after taking each puff may help. Your doctor may prescribe an antifungal medication to treat the thrush.

- Tremor and rapid or irregular heartbeat (palpitations) - these are usually harmless and diminish as treatment continues.

- Muscle cramps.

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):

- Pneumonia and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increase in phlegm production, change in phlegm colour, fever, tremor, increased cough, and increased breathing problems.

- Bruising and fractures.

- Inflammation of sinuses (a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache).

- A reduction in the amount of potassium in the blood (you may get an uneven heartbeat, muscle weakness, cramp).

#### Uncommon (affects less than 1 person in 100)

- Rash.
- Very fast heartbeat (tachycardia).

#### Rare (affects less than 1 person in 1000)

Allergic reactions: you may notice your breathing suddenly gets worse after using AIREST. You may be very wheezy and cough. You may also notice itching and swelling (usually of the face, lips, tongue, or throat).

**If you get these effects or if they happen suddenly after using AIREST, tell your doctor** or contact the emergency department of your nearest hospital.

- AIREST may affect the normal production of steroid hormones in the body, particularly if you have taken high doses for long periods of time. The effects includes:

- Slowing of growth in children and adolescents
- Thinning of the bones
- Cataract and glaucoma
- Weight gain
- Rounded (moon shaped) face (Cushing's Syndrome)

Your doctor will check you regularly for any of these side effects and make sure you are taking the lowest dose of AIREST to control your asthma.

- Uneven heart beat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking AIREST unless they tell you to stop.

- Increase in the amount of sugar (glucose) in your blood (hyperglycaemia). If you are diabetic, you may need to observe your blood sugar more often and possibly adjust your regular diabetes treatment.

- Changes in behavior such as anxious mood, sleep disturbances and unusual active or restless behavior (these effects are usually seen in children).

- Painful, swollen joints and muscle aches

*If you notice any side effects not mentioned in these instructions for use, inform your doctor and pharmacist.*

#### 5. How to store AIREST?

*Keep out of the reach and sight of children.*

Store at room temperature below 30 °C in a dry place.

#### Use in accordance with the expiration date.

*Do not use AIREST after the expiration date on the packaging.*

If you realize any defect in the product and/or its protective package, do not use AIREST and return it back.

#### Marketing Authorisation Holder and Manufacturer:

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